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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,158	12/11/2006	Mark E. Samuels	760050-154	4554

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,158	SAMUELS ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-118* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-32, 62-83, 86-90, 98-105 drawn to a method of identifying an agent that modulates HFE2A gene expression utilizing HEF2A gene or its expression product, isolated polynucleotides encoding HFE2 gene product, their expression products.

Group II, claim(s) 33-43, 91-97, drawn to a method of treating a disorder utilizing said modulators.

Group III, claims 44-54, drawn to a method of preventing a disorder comprising administering to an animal at risk of developing said disorder utilizing said modulators.

Group IV, claims 55-61, 106-107, 112-115, drawn to a method to diagnose individuals affected with disease of iron metabolism utilizing HFE2A gene mutation or polymorphism.

Group V, claims 84-85, drawn to a method of producing test data utilizing said HFE2 gene.

Group VI, claims 108, 110-111, 116-117, drawn to a method of diagnosing anemia comprising determining a change in HFE2A polypeptide levels.

Group VII, claims 109-111, 116-117, drawn to a method of diagnosing iron deficiency anemia comprising determining a change in HFE2A polypeptide levels.

In addition to inventions listed as Groups I-VII above each invention is additionally and independently directed to the following patentably distinct products of unrelated chemical structure and function (or method of use thereof):

(a) SEQ ID NO:10 or DNA encoding it.
(b) SEQ ID NO:11 or DNA encoding it.
(c) SEQ ID NO:12 or DNA encoding it.
(d) SEQ ID NO:23 or DNA encoding it.
(e) SEQ ID NO:24 or DNA encoding it.
(f) SEQ ID NO:25 or DNA encoding it.
(g) SEQ ID NO:26 or DNA encoding it.

(h) SEQ ID NO:27 or DNA encoding it.
(i) SEQ ID NO:28 or DNA encoding it.
When electing any of the inventions listed as Groups I-IV above applicant is advised to simultaneously elect an invention from groups (a)-(i) as well. **This is not a species election.**

Further, the inventions of Group II by itself is directed to the following patentably distinct methods of different steps and different end-points.
1) a method of treating hemochromatosis
2) a method of treating transfusion iron overload,
3) a method of treating thalassemia,
4) a method of treating porphyria,
5) a method of treating type I diabetes, and
6) a method of treatment of Type II diabetes.

For Group II invention, each method of Groups 1-6 is a separate and unrelated invention and must be elected independently in addition to electing a sequence from Groups (a)-(i) above. **This is not a species election.**

Furthermore, for Group IV invention, each of polymorphisms listed in Table I is a separate and unrelated invention and must be elected independently with a single invention from Groups (a)-(i) above. Again, **This is not a species election.**

The inventions listed as Groups I-VII above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Groups I, II, IV and VI are, HFE2A gene, modulators(or method of use thereof), and HFE2A gene products respectively which share no chemical or functional features.

Groups II are III share a special technical feature, namely modulators, by said inventions under PCT Rule 13.1 are not required to be rejoined because Group II already has a method of use of modulators.

Similarly Groups I, IV and V share a special technical feature, namely DNA, but again said inventions under PCT Rule 13.1 are not required to be rejoined because Group I already has a method of use of DNA.

Likewise Groups VI and VII share a special technical feature, namely HFE2A gene product, but said inventions under PCT Rule 13.1 are not required to be rejoined because Group VI already has a method of use of HFE2A gene product.

Additionally Groups II and III are generic to the following 4 distinct species of unrelated structure:

A) antibody, (B) antisense, (C) ribozyme and (D) a drug like molecule.

When electing any of the inventions of Group II and III applicant is advised to elect a single species from Groups A-D above.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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